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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,763	07/19/2004	Gunter Holzemann	MERCK-2903	3011
23599 7590 MILLEN, WHITE, 1	04/24/2007 ZELANO & BRANIG	EXAM	EXAMINER	
2200 CLARENDON BLVD.			CHANG, CELIA C	
SUITE 1400 ARLINGTON, VA	22201		ART UNIT	PAPER NUMBER
,			1625	
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SHORTENED STATUTORY PER	LIOD OF RESPONSE	MAIL DATE	DELIVERY MODE	
31 DAYS 04/24/2007		04/24/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

	Application No.	Applicant(s)	
	10/501,763	HOLZEMANN ET AL.	
Office Action Summary	Examiner	Art Unit	
	Celia Chang	1625	
The MAILING DATE of this communication app Period for Reply		l	
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).	
Status			
 Responsive to communication(s) filed on 19 Ju This action is FINAL. Since this application is in condition for alloware closed in accordance with the practice under E 	action is non-final.		
Disposition of Claims			
 4) ☐ Claim(s) 1-20 is/are pending in the application. 4a) Of the above claim(s) is/are withdraw 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) 1-20 are subject to restriction and/or expressions. 	vn from consideration.		
Application Papers	•		
9) The specification is objected to by the Examiner 10) The drawing(s) filed on is/are: a) access Applicant may not request that any objection to the orange of the correction of the orange of the	epted or b) objected to by the liderating on being objected to by the liderating of the drawing	e 37 CFR 1.85(a). ected to. See 37 CFR 1.121(d).	
Priority under 35 U.S.C. § 119		•	
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the prior application from the International Bureau * See the attached detailed Office action for a list of	s have been received. s have been received in Application ity documents have been received (PCT Rule 17.2(a)).	on No ed in this National Stage	
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	nte	

DETAILED ACTION

1. Claims 1-20 are pending.

2. Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-10, 15-16, drawn to compounds their composition and process of making thereof. If this group is elected, a further election of a single disclosed species is also required. Claims 11-12 to the extend that they are single active ingredient composition, will be prosecuted with the election.

Group II, claims 13-14, drawn to process of treating diseases using single active ingredient. If this group is elected, a further election of a single disclosed pathology and a single disclosed compound for treating the elected pathology is also required. Further restriction may be required.

Group III, claims 17-18, drawn to multiple ingredient composition and method of treating diseases using such multiple active ingredient composition. If this group is elected a further election of a single disclosed combination with every element named and a single disclosed pathology treatable by the combination is also required. Further restriction will be required.

Group IV, claims 19-20, drawn to intermediates.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the method of treating Alzheimer's disease can be practice with tacrine.

Inventions I, II and III are independent and distinct because merits for multiple active ingredient composition depends on the individual combination, the steps and sites of administration etc. which are independent and distinct from compound per se.

Invention IV is independent and distinct from inventions I-III since patentability of intermediates depends solely on the elements, bonding arrangements and chemical properties of the intermediates.

PCT Rule 13.1 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention").

PCT Rule 13.2 states that the unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B, Part 1(a), indicates that the application should relate to only one invention, of if there is more than one invention, inclusion is permitted if they are so slinked to form a single general inventive concept.

Annex B Part 1(b), indicates that "special technical features" means those technical features that as a whole define a contribution over the prior art.

Annex B Part 1(c), further defines independent and dependent claims. Unity of invention only is concerned in relation to independent claims. Dependent claims are defined as a claim that contains all the features of another claim and is in the same category as the other claim. The category of a claim refers to the classification of claims according to subject matter e.g. product, process, use, apparatus, means, etc.

Annex B Part 1(e), indicates that the permissible combinations of different categories of claims. Part 1(e)I, states that inclusion of an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product is permissible.

Annex B, Part 1(f), indicates the "Markush practice" of alternatives in a single claim. Part 1(f)I, indicates the technical relationship and the same or corresponding special technical feature is considered to be met when (A) all alternatives have a common property or activity, and (B) a common structure is present or all alternatives belong to a recognized class of chemical compounds. Further defining (B), Annex B, Part 1(f)(i-iii), the common structure must; a) occupy a large portion of their structure, or b) the common structure constitutes a structurally distinctive portion, or c) where the structures are equivalent and therefore a recognized class of chemical compounds, each member could be substituted for one another with the same intended result. That is, with a common or equivalent structure, there is an expectation relationship and the corresponding special technical feature result from a common (or equivalent) structure that is responsible for the common activity (or property). Part 1(f) iv, indicates that when all alternatives of a Markush grouping can be differently classified, it shall no, take alone, be considered justification for finding a lack of unity. Part 1(f)v, indicates that "When dealing with alternatives, if it can be shown that at least one Markush alternative is not

novel over the prior art, the question of unity of invention shall be reconsidered by the examiner"

In the instant case, at least one Markush alternative is not novel because prior art by Tang et al. CA 133:207639 anticipates group IV thus the lacking of unity of invention has been found.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be **allowable**, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai; In re Brouwer and 35 U.S.C.§ 103(b)," 1184 O.G. 86 (March 26, 1996).

Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include all the limitations of the product claims. Applicants are reminded of propriety of process of use claims in consideration of the "reach-trough" format, which is drawn to mechanistic, receptor binding or enzymatic functionality. Reach through claims are considered lacking of descriptive and enabling support from the specification. Thus, rejoinable process of use claims are those with particular disease named with efficacy support from the specification for treating the particular disease. Failure to do so may result in a loss of the right to rejoinder. For consideration of rejoinder, a method of use claim drawn to group II with a single pathology is recommended.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01. Filing of appropriate terminal disclaimer in anticipation of a rejoinder may speed prosecution and the process of rejoinder.

3. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and

specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie, Ph. D., can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang Apr. 17, 2007

Celia Chang
Primary Examiner
Art Unit 1625